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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,548	02/20/2001	Hana Koutnikova	ST00005	5202

29693 7590 07/08/2005

WILEY, REIN & FIELDING, LLP  
ATTN: PATENT ADMINISTRATION  
1776 K. STREET N.W.  
WASHINGTON, DC 20006

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/785,548

Applicant(s)

KOUTNIKOVA ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32,33,39,53 and 59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 39 is/are allowed.
- 6) ☒ Claim(s) 32,33,53 and 59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**  
***Response to Amendment***

1. The amendment filed on 4/18/05 has been entered.
2. The rejection of claims 63-65 under 35 U.S.C. 112, first paragraph, as containing new matter is withdrawn due to the cancellation of the claims.
3. The rejection of claims 38 & 63-65 are rejected under 35 U.S.C. 112, first paragraph, for lack of written description is withdrawn due to the cancellation of the claims.
4. The rejection of claims 38 & 63-65 are rejected under 35 U.S.C. 112, first paragraph, for lack of written description is withdrawn due to the cancellation of the claims.
5. The rejection of claims 32-33, 38, 53, 59 & 63-65 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the cancellation of the claims, or after further consideration by the Examiner to the previous amendment to the claims.
6. Applicant's arguments filed 4/18/05 have been fully considered but they are not deemed to be persuasive.
7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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8. Claim 39 is allowed.

9. Claims 32-33, 53 & 59 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper NOs: 13 (mailed 2/20/03), 20031217 & 20041116, and as follows.

As previously made of record, only the “**human**” PAP1 sequences of SEQ ID NOs: 2 & 15 have been described. No written description exists for any PAP1 polypeptides from any different species, yet the claims still encompass “peptides” from different species, which the current amendment to the claims does not correctly address. Additionally, as previously made of record, no written description exists for any allelic variants of the human protein of SEQ ID NO: 2 (except for the specific polypeptide of SEQ ID NO: 15) (i.e., as it relates to the genus recitation of “amino acid sequences of at least 95% identity to... SEQ ID NO: 2”), in which no **functional** language is further recited to adequately describe such allelic variants in base claim 32. Therefore, the current claims continue to not adequately meet the written description requirements under 35 U.S.C. 112, first paragraph, for the reasons extensively made of record; consistent with that held by the courts in *Fiers v. Revel*, *Fiddes v. Baird*, and *Univ. California v. Eli Lilly and Co.*, previously made of record. See MPEP 2163.

It is suggested that amending claim 32 to “ an isolated human polypeptide [compound]....”, along with incorporating the limitations of claim 33 into claim 32 should

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obviate this rejection. Accordingly, claims 53 & 59 should also be amended to reflect proper antecedent basis to base claim 32, when amended.

10. Claim 32, 53 & 59 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the PAP-1 protein of SEQ ID NO: 2, does not reasonably provide enablement for any variant PAP-1 molecules with no distinguishable and assayable functional characteristics, or for “nonfunctional” polypeptides, as currently claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper NOs: 13 (mailed 2/20/03), 20031217 & 20041116, and as follows.

As previously made of record, the claims still fail to recite adequate functional and assayable language for the skilled artisan to know “how to use” the instant invention, for the reasons previously made of record; consistent with the teachings of Rudinger previously made of record. Thus, Applicants’ arguments are not persuasive, for the reasons previously made of record in the previous Office actions for why structurally and **functionally** uncharacterized proteins are not reasonably enabled.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.  
July 6, 2005

**ROBERT C. HAYES, PH.D.**  
**PATENT EXAMINER**